The Falsified Medicines Directive

Sofia

19th May 2015

Counterfeit (Falsified) Medicines

Falsified Medicines Directive

European Legislation passed in July 2011

- The legislation requires at risk medicines to carry additional safety features
  - Unique code on each medicine pack
  - Each pack to have tamper evident device
- To enable the systematic verification of the authenticity of the medicine at the point of dispense

Delegated Acts

1. Detailed requirements driven by a Delegated Act
2. All Member States will have to implement exactly the same legislation

European Commission

Impact Assessment - Inclusions

Directive 2011/62/EC requires the Commission to perform a study assessing benefits, costs and cost-effectiveness of:

- the technical characteristics of the unique identifier;
- the options for the verification of the authenticity of the medicinal product bearing the safety features and the practical arrangements for such verification;
- the technical options for establishing and managing the repository system.

This study was conducted in the form of an impact assessment and finalised at the end of 2013.

Health and Consumers

In practice:

- The UI shall contain the following information:
  - **Manufacturer product code**
  - **Serial number**
  - **A national reimbursement number, if present**
  - **Batch number**
  - **Expiry date.**
- The UI will be carried by a 2D barcode (data matrix).

Impact Assessment – Outcome (II)

Objective 2: to introduce proportionate verification of the

In practice:

- *Medicines will be systematically checked-out at the dispensing point*
- *Wholesale distributors will verify the safety features when:*
  - ***The product is not obtained from the holder of the manufacturing authorisation or the holder of the marketing authorisation;***
  - ***The product is returned by another wholesale distributor or a pharmacy.***

Health and Consumers

Impact Assessment – Outcome (III)

Selected option: Establishment and management by stakeholders with supervision by the relevant competent authorities

European Commission

Impact Assessment – Outcome (III) – Cont'd

In practice:

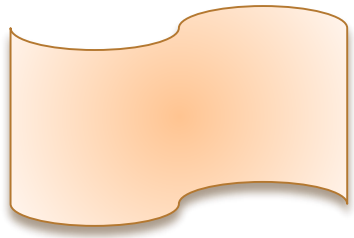
The manufacturers and parallel importers will have to ensure that:

- The unique identifier is placed on the pack for authentication;
- The serial number can be checked out at the dispensing point;
- The repository system is suitable to ensure authentication of medicinal products at the dispensing point;
- The response from the repository system is virtually instantaneous;
- The repository system guarantees the protection of commercial, confidential and personal data;
- The concerned competent authorities have full access to the repository system and can supervise its functioning.

Health and Consumers

Falsified Medicines Directive (FMD)

Pack **2D Code** **Anti-Tampering**

+  + 

=

Falsified Medicines Directive (FMD)

Parallel Trade

- Packs purchased by Parallel Traders will need to be 'checked-out' of the exporting markets
- Repackaged/relabelled packs will require new unique codes in the import market and 'checked-in' to the importing markets database
- Additionally the European Hub will reconcile export and import dose volumes to ensure parallel trade does not inadvertently become an entry point for falsified medicines

Falsified Medicines Directive (FMD)

Summary:

- 2D barcode will be fully harmonised across the EU
- Medicine authenticity will be guaranteed by an end-to-end verification system
- Risk-based verifications by wholesales
- Medicines will be systematically verified before being dispensed to patients
- The repository containing the unique identifiers will be set up and managed by stakeholders
- National competent authorities will be able to access and supervise the database.

FMD Timings

- The Delegated Acts will be adopted by the Commission by the end of Q2 2015
- Following a review by Council and Parliament the Delegated Acts will be published at the end of Q3/4 2015
- Manufacturers and other stakeholders will then have 3 years to implement the requirements in all European countries
- Stakeholders need to identify the service provider early, to schedule roll-out and get best possible pricing

Thank you

Graham Smith

Graham.Smith@aegate.com

Watch the Aegate video:- http://www.youtube.com/watch?v=zAOG1R0jrV4